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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,948	08/12/2003	Rajat Sethi	12695.6USD6	6989

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/639,948	SETHI ET AL.	
	Examiner	Art Unit	
	Dwayne C. Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the amendment of 11JUL2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1 and 6-16 are pending.

2. Claims 1 and 6-16 are rejected.

3. Claims 2-5 are cancelled as per the amendment of July 11, 2005

Response to Arguments

4. Applicant's arguments with respect to claims 1 and 6-16 have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

5. The information disclosure statement filed on July 11, 2005 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1 and 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman, J. G. in view of Lobel of U.S. Patent No. 3,282,778. Hardman, J. G., Editor-in-chief of Goodman & Gilman's THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 9TH Edition. Hardman, J. G. teaches of that congestive heart failure is one of the most common causes of death and disability in the industrialized nations. Hardman, J. G. also states that before initiating drug therapy for heart failure, it is important to eliminate or mitigate other potentially reversible cause of cardiac dysfunction, such as myocardial ischemia, cardiac arrhythmias, and hypertension, as

well as other causes, and Hardman, J. G. further teaches that primary hypertrophic cardiomyopathy often leads to thickened, poorly compliant ventricular walls with small ventricular volumes. In addition, Hardman, J. G. discloses that treatment must be tailored to the underlying pathophysiological process in an individual patient. One of the most common causes of heart failure is due to advanced coronary atherosclerosis. Hardman, J. G. also discloses that it is common practice in the art to interventional, pharmacological, and dietary therapies designed to slow the progression of or reverse coronary atherosclerosis should be initiated concurrently with the drug therapy (see page 809). In fact, it is common practice to administer the following well known pharmaceuticals for the treatment of heart failure, such as diuretics, (see pages 820-824), vasodilators (see pages (824-836), in particular, calcium channel blocker (see pages 829 and 831), angiotensin converting enzyme (ACE) inhibitors, (see pages 825-827 and 830), β-adrenergic receptor antagonists (see pages 831-835). Since Hardman, J. G. specifically provide guidance and instruction that it is common practice in the art to interventional, pharmacological, and dietary therapies designed to slow the progression of or reverse coronary atherosclerosis should be initiated concurrently with the drug therapy, one having ordinary skill in the art would have been motivated to administer as well as be motivated to maintain healthy diets, through intake and supplemental aids, such as the administration of a multi-vitamin and lower salt intake. In addition, Hardman, J. G. teach of the three forms of vitamin B_6, namely pyridoxine, pyridoxal, pyridoxamine, (see page 1562) and that pyridoxal phosphate is involved in several metabolic transformations of amino acids, (see page 1562). Hardman, J. G. also

teaches of the antioxidants of vitamin C (see pages 1568-1571) and vitamin E (see pages 1573 and 1585-1588). In fact, Hardman, J. G. provide explicit motivation to use antioxidants, such as vitamins A, C, and E in protection against cardiovascular and malignant diseases and that nutrient deficiency increases the risk for disease (see page 1573)

10. Lobel teaches of pharmaceutical compositions that contain cardiovascular drugs as well as various compounds of the pyridoxine family, inter alia, pyridoxamine, pyridoxal, pyridoxal phosphate complex and pyridoxamine phosphate complex, (see column 1). Accordingly, the skilled artisan is provided with various members of the pyridoxine family that may be used pharmaceutically to treat an individual in need thereof. Moreover, when the well-known compounds of the pyridoxine family, inter alia, pyridoxamine, pyridoxal, pyridoxal phosphate complex and pyridoxamine phosphate complex (as evidenced by Lobel) are combined with the teachings of Hardman, J. G. the instant claims are clearly rendered obvious, namely to treat the heart failure, in particular the heart failing aspect of hypertrophy.

11. Not only does the prior art of Hardman, J. G. and Lobel et al. teach of equivalence of vitamin B_6 and its pharmaceutically equivalent active metabolites, it is well established in the case law that a pharmaceutical and its active metabolites are inherent. Once the compounds of the prior art reference are administered to an individual in need thereof, the vitamin B_6 compound will be metabolized by the body and the presence of these metabolites, as well as their properties, are inherent with the administration of vitamin B_6 (pryidoxine), see Shering Corporation vs. Geneva

Pharmaceuticals, Inc. and Novarits Corporation and Teva Pharmaceuticals Usa, Inc. and Andrx Corporation, Andrx Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc. and Wyeth, Esi-Lederle, Wyeth Pharmaceuticals, and Wyeth Consumer Healthcare (formerly American Home Products Corporation, Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare) and IMPAX Laboratories, Inc. Apotex, Inc. and Novex Pharma, Copley Pharmaceutical, Inc. and GENPHARM, INC. (CAFC, 02-1540, -1541, -1542, -1543, -1544, -1545, -1546, -1547, -1548, -1549, 03-1021, -1022, -1023, -1025, -1027, 8/1/2003).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see http://pair-direct.uspto.gov. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
September 19, 2005